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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,088	06/20/2003	Mark B. Knudson	14283.2US01	9155

7590 07/26/2006
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EXAMINER

MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/600,088	Applicant(s) KNUDSON ET AL.	
	Examiner Michael G. Mendoza	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

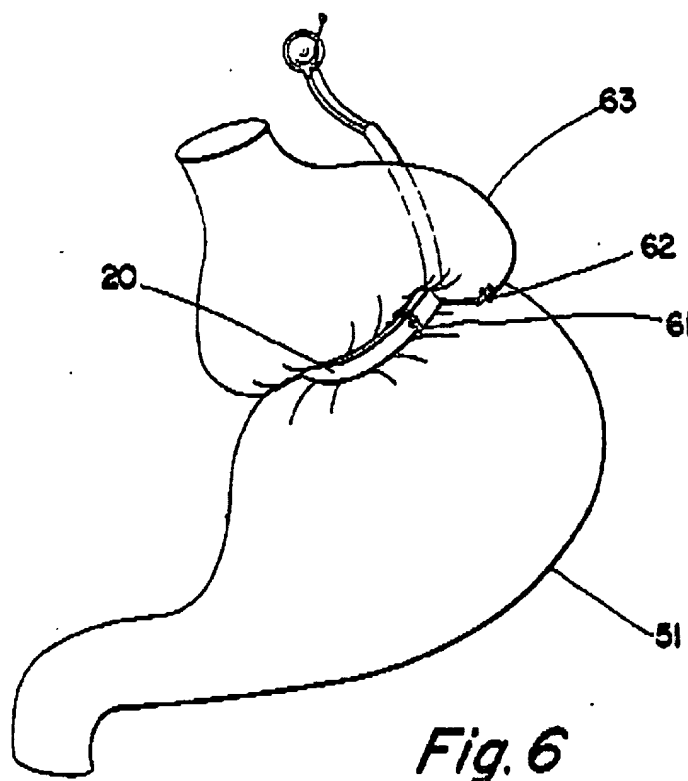
Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/16/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 25 May 2006 have been fully considered but they are not persuasive. The statement from the declaration does not provide evidence of no portion of the band of Cigaina is placed above the cardiac notch or on the esophagus. Both the instant application and Cigaina show placing a band that results in the relocation of the Cardiac notch, a lengthened esophagus, and reduced size of the fundus. The band of Cigaina is placed on the esophagus as shown in the figures. It is used for reshaping and does not form a pouch as shown in the figures, because it is placed on the esophagus. If a pouch was to be formed it would look like the attached figure.



Furthermore, the specification gives no criticality for placing the element as recited.

2. In response to applicant's arguments, the recitation "treating gastro-esophageal reflux disease (GERD) of a patient" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Cigaina WO 01/41671 A2.

5. Cigaina teaches a method/apparatus for gastro-esophageal reflux disease (GERD) of a patient comprising: accessing a juncture of an esophagus and a stomach of the patient on a distal side of a diaphragm of the patient with the esophagus and a fundus of the stomach intersection at a cardiac notch located at an original cardiac notch position; placing a reducing element at the junction with the reducing element selected to reposition the cardiac notch to a repositioned cardiac notch position more distal to a lower esophageal sphincter of the patient and define an extended esophageal portion; the reducing element sized for the reducing element to be placed around both a distal portion of the esophagus including surrounding a portion of the esophagus above the original cardiac notch portion and a proximal portion of the stomach, the placing including placing the reducing element around both the esophagus including surrounding a portion of the esophagus above the original cardiac notch portion and the stomach to create the extended esophageal portion with the reducing element restraining formation of a gastric pouch between proximal and distal ends of the reducing element; wherein the placing includes selecting the element to be selectively

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adjustable along a length of the element to selectively adjust a volume of the element to form an extended esophagus portion between the original cardiac notch position and the repositioned cardiac notch position; wherein the element includes a material positioned loosely on the esophagus and fundus and the adjusting includes gathering and securing the gathered material along a length of the element; wherein the element is secured to either the esophagus or the stomach to restrict movement of the element relative to a final positioning of the element; wherein the securing includes providing selected areas of the element with tissue in-growth areas (see figs. 2-4); and wherein the element includes a securing member 6 for securing the element.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cigaina.

8. Cigaina disclosed the claimed invention except for a plurality of separate elements. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plurality of separate elements since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

9. Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cigaina in view of Forsell US 2002/0193842 A1.

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10. Cigaina teaches a method/apparatus according to the above rejected claims. It should be noted that Cigaina fails to teach placing an implant adjacent an esophagus of the patient to create a restricted region.

11. Forsell teach a device with a common implant for electrically stimulating the cardia sphincter to increase sphincter tonus. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the implant of Forsell to allow the patient at any time to control the treatment of heart and reflux disease when various needs arise over a day, so that the patient always is satisfied (pg. 1, [0005]).

12. Cigaina/Forsell teaches the method/apparatus as above, wherein the implant can be actuated to at least partially close the esophagus and abate reflux of contents of a stomach of the patient retrograde with the esophagus; wherein the implant includes actuation an artificial sphincter at least partially surrounding the esophagus to change states from an open state to an at least partially closed state, the artificial sphincter in the open state permitting substantially unimpeded food flow through the esophagus into the stomach, the artificial sphincter in the at least partially closed position at least partially closing the esophagus and abating reflux of contents of the stomach retrograde with the esophagus (pg. 4, [0046]); wherein the actuation of the implant is initiated by the patient (pg. 1 [0001]); and wherein the actuation of the implant is initiated by a controller operatively connected to electrodes and having an input operatively connected to organ sensors (pg. 1, [0012]).

Allowable Subject Matter

13. Claim 4 is allowable over the prior art of record.

The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record fails to teach or render obvious the overall claimed method for treating gastro-esophageal reflux disease (GERD) of a patient comprising: an element including a slit along a length thereof and adjusting includes altering a spacing of the slit.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

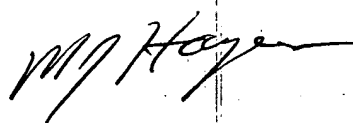
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MM



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER